

K063842

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**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

APR 17 2007

<b>Submitter</b>		
Name:	Oratio B.V.	
Street:	Cole Porterhof 168	
ZIP/Postal Code, City:	1628 TN HOORN	
Federal State:	NH	
Country:	The Netherlands	
Establishment Registration Number:	KvK Hoorn 37104336	
Contact:	Prof.dr.ir. Jef M. van der Zel Chief Scientific Officer	
Phone:	+31 229 247660	
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E-mail:	jmvanderzel@wxs.nl	
<b>Name of Device</b>		
Proprietary Name:	Cyrtina® BioZyram® Sakura® Interaction	
Classification Name:	Dental ceramic Porcelain powder for clinical use	
Common Name:	All-ceramic core material All ceramic overlay material	
<b>Predicate Devices</b>		
LAVA Frame	K 011394 (3M ESPE)	
Denzir	K 984201 (Dentronic)	
DCZirkon	K 001815 (Austenal)	
Willi Geller Creation Porcelain	K 981490 (Jensen Industries)	
OPC 3G All-ceramic system	K 994435 (Jeneric Pentron)	
IPS Empress 2	K 982616 (Ivoclar)	
Cercon Ceram Porcelain	K 011333 (Dentsply)	
KATANA Zirconia	K 050160 (Noritake Company)	



<b>Description for the Premarket Notification</b>	
<u>Intended Use</u>	
	<p>The CYRTINA SYSTEM is intended to fabricate all-ceramic dental devices like definite crowns and bridges. The Cyrtina System consists of two different materials:</p> <p>Cyrtina® BioZyram® is a core material made of zirconia. It is provided as green, shaded hexblocks especially developed for processing for milling at Cyrtina® Center. The five shades are combined with the grouped Cyrtina® Ceram shades</p> <p>Sakura® Interaction is an all-ceramic overlay material in powder form developed for veneering Cyrtina® BioZyram® substructure by layering to provide esthetics and characterization for fixed prosthodontic devices that include both anterior and posterior crowns/bridges and for implant abutments.</p> <p>Sakura® Interaction consists of Liner/Dentin/Transparent/Incisal all-ceramic veneering material. The final restoration shade matches 16 Vita Lumen shades and four Bleach shades.</p> <p>Cyrtina® dental restorations are fabricated according to a dental impression which is scanned into a computing device. By CAD/CAM technology unfashioned zirconia blocks of Cyrtina® BioZyram® are milled in Cyrtina® Center. After the dental appliance has been milled the piece is sintered at a temperature of 1400°C. For esthetic reasons, the ceramic crown, bridge or abutment, resp. is veneered by Sakura® Interaction.</p> <p>Cyrtina® dental restorations have been on the European market since 2000 with over twenty thousand units placed.</p>
<u>Technological characteristics</u>	
	<p>All chemical ingredients for the core material and the veneer and heat-press material are already contained in predicate devices. Additionally, biocompatibility tests were carried out for the core and veneer/press material. The results show that Cyrtina® is a safe device.</p> <p>To provide evidence for the effectiveness of the Cyrtin® system, the physical and mechanical properties have been compared to predicate devices.</p> <p>We believe that the prior use of the components of CYRTINA SYSTEM in legally marketed devices, the performance data provided, the biocompatibility test results, and the historical use of the device in Europe support the safety and effectiveness of the CYRTINA SYSTEM.</p>





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jef M. van der Zel  
Chief Scientific Officer  
Oratio B.V.  
Cyrtina Center Zwaag  
Cole Porterhof 168  
1628 TN Hoorn  
THE NETHERLANDS

APR 17 2007

Re: K063842

Trade/Device Name: CYRTINA SYSTEM, Cyrtina® BioZyram, Sakura® Interaction  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder for Clinical Use  
Regulatory Class: II  
Product Code: EIH  
Dated: March 14, 2007  
Received: April 5, 2007

Dear Mr. Jef M. van der Zel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

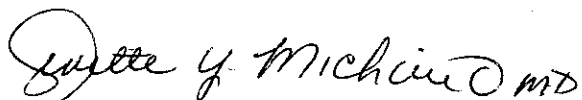
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K063842

INDICATIONS FOR USE STATEMENT

(As Required by 21 C.F.R. §801.109)

510(k) Number:

K063842

Device Name:

CYRTINA SYSTEM  
Cyrtina® BioZyram  
Sakura® Interaction

Indications for Use:

The Cyrtina system is intended for CAD/CAM fabrication of allceramic dental restorations.  
The system is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use: x

OR

Over-the counter use: ☐

(Per 21 CFR 801.109)

(optional Format 1-2-96)

.....  
(Division Sign-Off)

Division of Dental, Infection Control,  
And General Hospital Devices

510(k) Number .....

*[Signature]*

.....  
Division of Dental, Infection Control, General Hospital,  
And General Hospital Devices

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